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General Note
Article is recommended to print as digital color version in recycled paper.

KANUMA (SEBELIPASE ALFA)

Company: Alexion; Approved by December 2015

Specific Treatments: Lysosomal Acid Lipase (LAL) deficiency

General Information
Kanuma is specifically indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency. It is supplied as a solution for intravenous infusion. The recommended starting dosage is 1 mg/kg administered once weekly as an intravenous infusion. For patients who do not achieve an optimal clinical response, increase to 3 mg/kg once weekly.

Mechanism of Action
Kanuma (sebelipase alfa) is a hydrolytic lysosomal cholesteryl ester and triacylglycerol-specific enzyme. LAL deficiency is an autosomal recessive lysosomal storage disorder characterized by a genetic defect resulting in a marked decrease or loss in activity of the lysosomal acid lipase (LAL) enzyme. The primary site of action of the LAL enzyme is the lysosome, where the enzyme normally causes the breakdown of lipid particles including LDL-c. Deficient LAL enzyme activity results in progressive complications due to the

lysosomal accumulation of cholesteryl esters and triglycerides in multiple organs, including the liver, spleen, intestine, and the walls of blood vessels. The resulting lipid accumulation in the liver may lead to increased liver fat content and progression of liver disease, including fibrosis and cirrhosis. Lipid accumulation in the intestinal wall leads to malabsorption and growth failure. In parallel, dyslipidemia due to impaired degradation of lysosomal lipid is common with elevated LDL-c and triglycerides and low HDL-cholesterol (HDL-c). Sebelipase alfa binds to cell surface receptors via glycans expressed on the protein and is subsequently internalized into lysosomes. Sebelipase alfa catalyzes the lysosomal hydrolysis of cholesteryl esters and triglycerides to free cholesterol, glycerol and free fatty acids.

Side Effects
Adverse effects associated with the use of Kanuma may include: diarrhea, vomiting, fever, rhinitis, anemia, cough, nasopharyngitis, urticaria

UPTRAVI (SELEXIPAG)

Company: Actelion Pharmaceuticals; Approved by December 2015

Specific Treatments: pulmonary arterial hypertension

General Information
Uptravi (selexipag) is a prostacyclin receptor agonist, which exerts vasodilating effects. It is specifically indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. It is supplied as tablets for oral administration. The recommended starting dose of Uptravi is 200 micrograms (mcg) given twice daily. Tolerability may be improved when taken with food. The dose should be increased in increments of 200 mcg twice daily, usually at weekly intervals, to the highest tolerated dose up to 1600 mcg twice daily. If a patient reaches a dose that cannot be tolerated, the dose should be reduced to the previous tolerated dose. Do not split, crush, or chew tablets.

Mechanism of Action
Uptravi (selexipag) is an oral prostacyclin receptor (IP receptor) agonist that is structurally distinct from prostacyclin. Selexipag is hydrolyzed by carboxylesterase 1 to yield its active metabolite, which is approximately 37-fold as potent as selexipag. Selexipag and the active metabolite are selective for the IP receptor versus other prostanoid receptors (EP1-4, DP, FP and TP).

Side Effects
Adverse effects associated with the use of Uptravi may include: headache, diarrhea, jaw pain, nausea, myalgia, vomiting, pain in extremity, flushing

ZURAMPIC (LESINURAD)

Company: AstraZeneca; Approved by December 2015

Specific Treatments: hyperuricemia associated with gout

General Information
Zurampic is specifically indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. It is supplied as tablets for oral administration. The recommended dose is 200 mg once daily in combination with a xanthine oxidase inhibitor, including allopurinol or febuxostat. The maximum daily dose is 200 mg.

Mechanism of Action
Zurampic (lesinurad) reduces serum uric acid levels by inhibiting the function of transporter proteins involved in uric acid reabsorption in the kidney. Lesinurad inhibited the function of two apical transporters responsible for uric acid reabsorption, uric acid transporter 1 (URAT1) and organic anion transporter 4 (OAT4), with IC50 values of 7.3 and 3.7 μM, respectively. URAT1 is responsible for the majority of the reabsorption of filtered uric acid from the renal tubular lumen. OAT4 is a uric acid transporter associated with diuretic-induced hyperuricemia. Lesinurad does not interact with the uric acid reabsorption transporter SLC2A9 (Glut9), located on the basolateral membrane of the proximal tubule cell.

Side Effects
Adverse effects associated with the use of Zurampic may include: headache, influenza, blood creatinine increased, gastroesophageal reflux disease

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ALECENSA (ALECTINIB)

Company: Roche; Approved by December 2015

Specific Treatments: ALK-positive, metastatic non-small cell lung cancer

General Information

Alecensa is specifically indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancers (NSCLC) who have progressed on or are intolerant to crizotinib. It is supplied as a capsule for oral administration. The recommended dose is 600 mg orally twice daily, taken with food. Administer until disease progression or unacceptable toxicity. Please see drug label for specific dose modifications.

Mechanism of Action

Alecensa (alectinib) is a kinase inhibitor that targets ALK and RET. In nonclinical studies, alectinib inhibited ALK phosphorylation and ALK-mediated activation of the downstream signaling proteins STAT3 and AKT, and decreased tumor cell viability in multiple cell lines harboring ALK fusions, amplifications, or activating mutations. The major active metabolite of alectinib, M4, showed similar in vitro potency and activity.

Side Effects

Adverse effects associated with the use of Alecensa may include: fatigue, constipation, edema, myalgia

VISTOGARD (URIDINE TRIACETATE)

Company: BTG; Approved by December 2015

Specific Treatments: fluorouracil or capecitabine overdose

General Information

Vistogard is specifically indicated for the emergency treatment of adult and pediatric patients. It is supplied as oral granules for oral administration. Mix each Vistogard dose with 3 to 4 ounces of soft foods such as applesauce, pudding or yogurt and ingest within 30 minutes. Do not chew the granules. Drink at least 4 ounces of water. The recommended dose for adults is 10 grams (1 packet) orally every 6 hours for 20 doses, without regard to meals. The recommended dose for pediatrics is 6.2 grams/m2 of body surface area (not to exceed 10 grams per dose) orally every 6 hours for 20 doses, without regard to meals.

Mechanism of Action

Vistogard (uridine triacetate) is a pyrimidine analog. Following oral administration, uridine triacetate is deacetylated by nonspecific esterases present throughout the body, yielding uridine in the circulation. Uridine competitively inhibits cell damage and cell death caused by fluorouracil.

Side Effects

Adverse effects associated with the use of Vistogard may include: vomiting, nausea, diarrhea

BRIDION (SUGAMMADEX)

Company: Merck; Approved by December 2015

Specific Treatments: reversal of neuromuscular blockade induced by rocuronium and vecuronium in adults undergoing surgery

General Information

Bridion is specifically indicated for the reversal of neuromuscular blockade induced by rocuronium and vecuronium in adults undergoing surgery. It is supplied as an injection for intravenous administration. Monitor for twitch responses to determine the timing and dose for Bridion administration.

Mechanism of Action

Bridion (sugammadex) is a modified gamma cyclodextrin. It forms a complex with the neuromuscular blocking agents rocuronium and vecuronium, and it reduces the amount of neuromuscular blocking agent available to bind to nicotinic cholinergic receptors in the neuromuscular junction. This results in the reversal of neuromuscular blockade induced by rocuronium and vecuronium.

Side Effects

Adverse effects associated with the use of Bridion may include: vomiting, pain, nausea, hypotension, headache.

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